Attachment 8.1.2 Waste Management and Waste Hierarchy

1.0 WASTE STREAMS AND HANDLING

The proposed development (addition of a production building and main emission point) will give rise to a variety of waste streams from process and non-process related activities. The operations of the existing installation generate two main categories of waste – hazardous and non-hazardous waste.

Attachment 8.1 outlines the different existing and anticipated waste types by List of Waste (LoW) Code and includes further detail on the period or periods of generation of the waste. The quantities are based on the 2019 figures for the existing installation. As the quantities presented are estimates only, the final quantities will be advised to the Agency in due course as part of the Annual Environmental Report for the installation.

This Attachment does not address the recovery of waste ethanol which is considered a product and is addressed in Section 4.3 of this application.

1.1 Collection and Storage of Waste Onsite

The Standard Operating Procedure SOP_002858 'Collection, Storage, Disposal and Monitoring of Waste' outlines all waste management procedures. The EHS Department provides backup technical information and support and is responsible for overseeing and ensuring compliance with this SOP.

When waste is generated, the department generating the waste is responsible for the disposal of the waste. The waste is isolated, identified and labelled using an ID label quoting the chemical(s), hazards, date of generation of waste, LEO ID and any other important information. The waste is evaluated for immediate hazards either to personnel or equipment Material Safety Data Sheets. If required, waste can be transferred to an alternative location on site if this reduces hazards e.g. to fix a broken acid line the acid must be removed to allow safe access to the area.

The waste is stored where it will not present a danger either from inherent hazards or accident by traffic flow or incompatibility (e.g. oxidiser and flammable substance).
The waste is then disposed of in accordance with the sections below.

1.1 Hazardous Waste

1.1.1 Hazardous Solid Wastes

Hazardous solid wastes generated at the facility include the following:

- Packaging containing residues of or contaminated by hazardous substances;
- Solid waste containing dangerous substances;
- Contaminated solid waste e.g. absorbents, cloths, PPE etc;
- Fluorescent tubes;
- Inorganic hazardous waste; and

- Organic solid hazardous waste.

All solid wastes are shipped off-site for disposal/recovery as per Standard Operating Procedure (SOP) 002858 or else transported offsite for treatment in Ireland.

Following development of the new carbon abatement system, activated carbon from the carbon beds will be changed out as required by the vendor and the spent carbon will be sent offsite of reuse/disposal.

It is anticipated that the spent activated carbon would be shipped to mainland Europe (Germany) where it would be re-processed to make “substitution fuel”. Incineration plants or cement plants which have a high energy demand often use “substitution fuel” as an alternative to fossil fuels such as oil or coal. The use of “substitution fuel” is particularly well suited to the process conditions found in cement or incineration plants and saves natural resources, reduces CO2 emissions and leaves very little waste as the ash fraction produced is often used elsewhere. This is the anticipated method only, and the final disposal method will be provided by the vendor who manages the change out.

1.1.2 Hazardous Aqueous Wastes

Hazardous aqueous wastes generated at the facility include the following:

- Waste acids and bases;
- Laboratory smalls; and
- Organic solvent waste.

A contractor is appointed to remove the hazardous waste from site and/or treat the hazardous waste. A valid waste permit is requested from the appointed contractor for the company who performs the final disposal of the waste before any waste is collected. It is verified that the appointed contractor complies with the current ADR regulation (carriage of dangerous goods by road). The contractor is requested to complete a WTF form as required for the transport of hazardous waste and a Trans Frontier Shipment (TFS) Form if the waste is being transferred overseas.

When the contractor arrives at the site to collect the waste, a waste disposal record is completed which records details of the final disposer and transporter of the waste. Security carry out checks on the collection vehicle as per the Vehicle and Driver Checklist for hazardous waste disposal and check that the waste is suitably secured before allowing the vehicle to leave the site.

After collection, when the waste is disposed/recycled, the contractor will issue LEO Pharma with a certificate of destruction/reuse which is then filed with the relevant waste disposal record.

Waste ethanol from the distillation columns following malfunction during the regeneration process may also be generated as a waste for offsite treatment. In 2019 approximately 5.5 tonnes of ethanol and water waste was sent offsite for

recovery/reclamation is shown in Attachment 8-1-2. This waste is separate from the regenerated ethanol that is sent offsite for re-use in a different sector (see Section 4.3 of the application).

1.2 Non-Hazardous Waste

1.2.1 Non-Hazardous Solid Wastes

Non-hazardous solid wastes generated at the installation include:

- Paper and cardboard;
- Plastic packaging;
- Commercial and Industrial bulky waste;
- Confidential paper;
- Metal (aluminium drums); and
- WEEE; and

A contractor is appointed to remove the non-hazardous waste from site and/or treat the non-hazardous Waste. A valid waste permit is requested from the appointed contractor for the company who performs the final disposal of the waste before any waste is collected.

When the contractor arrives at the site to collect the waste, a waste disposal record is completed which records details of the final disposer and transporter of the waste. Security carry out checks on the collection vehicle as per the Vehicle and Driver Checklist for Hazardous Waste Disposal and check that the waste is suitably secured before allowing the vehicle to leave the site. The completed waste disposal record with the attached final disposers waste permit is then filed with security at reception.

1.2.2 Wastewater

Industrial effluent and domestic effluent are generated at the existing facility and are discharged to the Irish Water foul sewer at Emission Point SE-1.

This waste stream is not addressed in this report. Further detail is provided in the section on wastewater outlined in Attachment 4.1 Operational Report.

2.0 ON AND OFF-SITE ARRANGEMENTS FOR THE RECOVERY OR DISPOSAL OF SOLID AND LIQUID WASTES

The management of waste will continue in accordance with the existing procedures in place at the installation and in accordance with the requirements of LEO Pharma's IE Licence (Licence Reg. No. P0091-002). The LEO Pharma EHS Department are responsible for overseeing the implementation of waste management procedures. The EHS department also ensures that all waste contractors used by the installation and all recovery/disposal outlets, are suitable for use, appropriately authorised and audited, as required.

Waste is transported to the approved waste contractor in a manner which does not adversely affect the environment and is in compliance with all relevant legislation. It is ensured that the approved waste contractors and hauliers have the appropriate permits and records of waste management operations are retained for inspection.

2.1 Waste Disposal Register

The documentation required for the disposal of waste depends on the type of waste and its destination. Documentation must be completed prior to collection of the waste. A copy of all documentation is filed in the Waste Disposal Register as required by the EPA.

The following information is retained:

- Reference information for waste disposal e.g. EWC List;
- Names and telephone numbers of waste disposal contractors;
- A copy of the current Waste Management Permit for each contractor used for either transport of the waste or waste disposal; and
- Waste Disposal Record and associated documentation for each consignment of waste.

All reference information and waste disposal company lists are kept up to date with current Waste Management Permits. All documentation for each consignment of waste is filed together e.g. Waste Disposal Record, WTF form, Certificates of Destruction etc.

3.0 WASTE HIERARCHY

LEO Pharma Cork is committed to minimising the quantities of hazardous and non-hazardous waste generated from direct and indirect manufacturing activities. The waste hierarchy states that the most preferred option is prevention of waste, followed by preparing for reuse and recycling/recovery, energy recovery (i.e. incineration) and, least favoured of all, disposal. In order to minimise the potential impact to the environment, LEO Pharma Cork will seek to meet the intent of the waste management hierarchy (Refer to Figure 1 below).

The new and existing production processes have been designed with waste prevention/reduction in mind (although it should be noted that there are certain restrictions in terms of Good Manufacturing Practice (GMP) requirements which may unavoidably result in waste generation). Continuous improvement techniques are key to the operation of the facility as set out in the Environmental Management System (EMS).

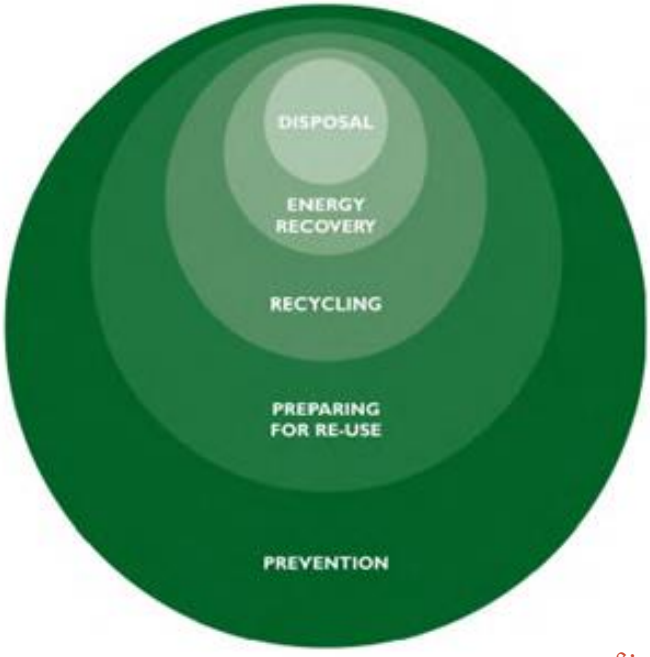

Figure 1 Revised Waste Management Hierarchy

It is part of the LEO corporate environmental policy that the installation must use the highest-prioritized waste-elimination/disposition method in the following list that is practicable for the particular waste stream:

a. Waste reduction at source of generation (waste elimination and prevention)

b. Reuse or recycling on site

c. Reuse or recycling off site at another company installation (assuming the waste-receiving site satisfies all regulatory requirements to do this)

d. Reuse or recycling off site at a properly licensed and properly operated non-company waste-receiving site

e. Incineration with energy recovery

f. Waste treatment, incineration without energy recovery or other destruction method.

g. Landfilling or other land application

Approximately 10.2 tonnes of Hazardous waste were generated in 2019. The following is the treatment breakdown for these wastes:

- 89.7% sent for Recycling/Recovery
- 10.3% sent for Disposal

Approximately 85.5 tonnes of Non-Hazardous waste were generated in 2019. The following is the treatment breakdown for these wastes:

- 100% sent for Recycling/Recovery
- 0% sent of Disposal

4.0 WASTE PREVENTION / MINIMISATION OF WASTE

LEO Pharma Cork is committed to minimising the environmental impact of its operations and the proposed waste management process for the installation is considered an essential and integral component in the efficient operation of the installation.

Waste minimisation is a fundamental philosophy in all departments and activities. The site maintains an ongoing programme to identify and prioritise waste minimisation opportunities. Progress on achieving waste reduction goals is discussed at least annually as part of the Management Review of the EMS and documented in the Annual Environmental Report.

The raw materials used in the pharmaceutical products produced at the site are extremely valuable therefore the minimisation of waste is crucial to the commercial success of the site.

5.0 WASTE RECYCLING AND RECOVERY

Improvements in environmental performance will be encouraged in the EMS associated with the IE Licence by setting a series of objectives and targets commonly associated with reducing resource material use (e.g. water, energy, paper) and waste production generally. LEO Pharma Cork will undertake the establishment of meaningful targets for improvements in the areas of waste reduction throughout the lifetime of the operation of the installation.

Food waste will be managed in accordance with the Waste Management (Food Waste) Regulations 2009.